

Attachment 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

R.J. REYNOLDS TOBACCO COMPANY;
SANTA FE NATURAL TOBACCO
COMPANY, INC.; ITG BRANDS, LLC;
LIGGETT GROUP LLC; NEOCOM, INC.;
RANGILA ENTERPRISES INC.; RANGILA
LLC; SAHIL ISMAIL, INC.; and IS LIKE
YOU INC.;

CIVIL ACTION NO. 6:20-cv-00176

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION; UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; STEPHEN M. HAHN,
in his official capacity as Commissioner of the
United States Food and Drug Administration;
and ALEX AZAR, in his official capacity as
Secretary of the United States Department
of Health and Human Services;

Defendants.

DECLARATION OF LAMAR W. HUCKABEE

I, LAMAR W. HUCKABEE, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

Introduction & Issues to be Addressed

1. I am the Senior Vice President for Combustible Tobacco Products at R.J. Reynolds Tobacco Company ("RJRT"). RJRT is an indirect wholly owned subsidiary of Reynolds American, Inc. RJRT was founded in 1875 and today is the second-largest tobacco company in the United States and manufactures several leading brands of cigarettes (such as Newport, Camel,

and Pall Mall). I have a bachelor's degree from The University of Texas and a Master of Business Administration from Pepperdine University.

2. I have been employed by RJRT from 2016 to the present. Over the course of my employment at RJRT, I previously held the position of Vice President of Strategy and Planning and my work related to the marketing of the company's brands. In my current position, which I have held since November 2018, I have responsibility for the marketing of RJRT's cigarette brands, including overall brand strategic planning, product development, advertising and marketing communications with consumers, including packaging and point of sale marketing at retail.

3. I am also Senior Vice President of Santa Fe Natural Tobacco Company, Inc. ("SFNTC") and, in that capacity, have responsibility for the marketing of the Natural American Spirit cigarettes manufactured by SFNTC.

4. This declaration describes the numerous actions and significant costs that will be incurred by RJRT and SFNTC to comply with the new graphic-warning requirements imposed by the Food and Drug Administration ("FDA") detailed in the Final Rule entitled "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements" on March 18, 2020, 85 Fed. Reg. 15,638 (the "Rule"), issued under the Family Smoking Prevention and Tobacco Control Act, Pub. Law No. 111-31, 123 Stat. 1776 (2009) (the "Act").

5. The Rule requires significant changes by both RJRT and SFNTC for their cigarette brands in terms of package design and operationally from the current warning regime in which there are four specified Surgeon General's warnings which must appear on the side of the pack (and elsewhere depending on the media or packaging) and rotate on a quarterly basis. 85 Fed. Reg. at 15,709. By contrast, the Rule now mandates 11 new warnings (text and graphics) that will

appear on the top 50% of the front and back of each pack (and elsewhere depending on the packaging or marketing media), imposes requirements regarding the appearance of the warnings on packaging (e.g., on packs with flip-top lids, the lid cannot split the letters in the warning) and requires random and equal distribution of the warnings during manufacturing over the course of a year, within a commercially reasonable tolerance. 85 Fed. Reg. at 15,693, 15,708–09.

6. FDA recognizes that implementing changes of this magnitude is a significant undertaking and initially provided fifteen months for manufacturers to do so from the publication date of the Rule. Specifically, the Rule’s graphic-warning requirements were drafted to apply to cigarette packaging manufactured on or after the effective date (fifteen months after the date the Rule is published), and to prohibit any cigarette packaging introduced into commerce on or after thirty days after that effective date that fails to bear the new warnings. *Id.* at 15,694.

7. Following FDA’s issuance of the Rule, the global outbreak of COVID-19 prompted the parties to file a joint motion requesting a 120-day postponement of the Rule’s effective date. On May 8, 2020, the Court granted that motion, postponing the effective date of the Rule and related requirements from June 18, 2021, to October 16, 2021.

Implementation of Packaging Changes

8. As noted above, the Rule requires that RJRT and SFNTC change the packaging graphics on every style of packaging and cartons for each of its respective cigarette products. Combined, RJRT and SFNTC have over 170 separate styles of cigarette products. These products are packaged in individual packs, cartons, and cases. As a result, RJRT and SFNTC, collectively, will need to revise and produce over 390 distinct printed packaging (pack and carton) designs.

9. In order to meet the effective date of the Rule (as it now stands, given the Court’s postponement), RJRT and SFNTC, collectively, must take the following steps:

10. First, RJRT and SFNTC employees, as well as affected suppliers must determine the steps and resources necessary to modify the current printing process to accommodate the number of packaging revisions required as well as to comply with the Rule's requirement relating to the random and equal display and distribution of the required warnings. This process has been underway, involving approximately 1,000 hours by company employees and suppliers.

11. Second, to print the redesigned packaging, RJRT and SFTNC, collectively, must purchase approximately 6,000 printing cylinder bases and additional tooling (e.g., cutting, creasing and embossing tools). The blank metal printing cylinders must each be engraved to apply the ink for the redesigned cigarette packaging. The cost of these cylinder bases, additional tooling and engraving is estimated to exceed \$15 million. Some of these costs have already been incurred, but a large proportion of this amount has not yet been incurred. For example, the work to engrave the cylinders will take several months and must begin within ten months after the Rule is published (taking into account the 120-day postponement of the effective date).

12. Third, RJRT and SFNTC must retain graphics design firms and/or marketing firms to create the redesigned packaging to work with the companies' brand teams. This will be time-consuming and expensive. Since the Rule significantly alters and severely limits the physical space for brand graphics and text on cigarette packaging, it is necessary to carefully evaluate these designs. This work must commence almost immediately. I estimate that it will take several months to complete and require approximately 3,000 hours of employee and supplier time, and cost RJRT and SFNTC, collectively, more than \$1 million, and must begin a few months after the Rule is published (taking into account the 120-day postponement of the effective date).

13. Fourth, RJRT and SFNTC must then devote substantial employee time to review and approve the redesigned cigarette packaging and operational changes necessary to implement

the Rule. The approval process will be extensive given the magnitude of the required packaging changes and the accompanying manufacturing and operational implications of the Rule. Numerous departments—including Consumer Marketing, Consumer Relations, Legal and External Affairs, Scientific and Regulatory Affairs, Manufacturing, Operations, Procurement, and Trade Marketing, among others—will need to be involved, and this review and approval process will take several months to complete. These activities are estimated to require at least 300 hours of employee time, collectively.

14. Finally, after modified packaging designs have been approved, the cylinders to print them must be engraved, as described above in paragraph 11.

Implementation of Other Marketing Changes

15. The Rule's revised warnings must be revised not only in packaging, but also in advertising. The Rule requires the top 20% of all advertising to contain the modified warning; thus, existing brand advertising will also need to be revised. Most immediately, this impacts brand websites and retail point-of-sale advertising. For example, RJRT and SFTNC, collectively, will need to redesign, print and replace numerous point-of-sale communications at each of approximately 200,000 retailers. New warning-compliant advertising will need to be designed, coded (for brand websites), or printed and installed (removing non-compliant advertising in the process) (for point of sale). This work is estimated to involve thousands of hours of employee and supplier time and cost approximately \$10 million.

Deadline to Switch to Manufacturing of Redesigned Packaging

16. In order to produce the inventory necessary to comply with these deadlines, RJRT and SFNTC will need to begin manufacturing cigarettes in compliant packaging beginning at least three months prior to the Rule's effective date. If the Rule were invalidated after this point, RJRT

and SFNTC would have an inventory of cigarettes carrying the invalidated warnings and reflecting costs exceeding \$200 million because cigarette packages that fail to carry the correct FDA-mandated warning are “misbranded” under the Act and could not be lawfully sold. 85 Fed. Reg. 15,709–10. These “misbranded” cigarettes cannot be re-packaged, and the value of the reclaimed tobacco is nominal. In addition, it is estimated that RJRT and SFNTC would incur costs of approximately \$5.2 million in unusable packaging materials.

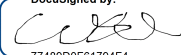
Summary and Conclusion

17. The time estimates provided in this declaration were made before the extent of the coronavirus’s impact on business operations was being felt. It is now becoming apparent that the virus is going to affect RJRT’s and SFNTC’s compliance efforts in a variety of ways. At a minimum, communication between company employees let alone with third party suppliers must be done electronically. The inability to conduct in-person meetings together with restrictions imposed by state and local orders governing how our third-party partners operate has and will cause certain levels of disruption in the near term. In short, the uncertainty caused by COVID-19 makes any compliance effort inherently more challenging and unpredictable. The full ramifications of the virus, and hence its impact on the estimates provided above, remain unclear. That said, given current interruptions in the normal work environment, I believe the estimates provided in this declaration will likely need to be increased, perhaps by 20%, particularly given the substantial amount of coordination across the businesses, and with third parties, that will be necessary to implement the Rule.

18. For the reasons described above, the logistical, design and planning issues to implement the Rule on a nationwide basis are extraordinary. Absent further relief from the Court,

RJRT and SFNTC will have no choice other than to continue with efforts to implement the Rule, as detailed above, during the period while the legality of the Rule is determined.

Executed on May 13, 2020

DocuSigned by:

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Wade Huckabee